K092388

JAN 21 2010

510(K) SUMMARY

DuraGen Plus® Dural Regeneration Matrix – Spinal Matrix and

Integra™ SpinalMend™ Dural Regeneration Matrix

Submitter's name and address:

Integra LifeSciences Corporation
311 Enterprise Drive
Plainsboro, NJ 08536 USA

Contact person and telephone number:

Candice Arner
Regulatory Affairs Associate
Integra LifeSciences Corporation
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Plainsboro, NJ 08536 USA
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Date: July 31, 2009

Name of the device:

Proprietary Name:	DuraGen Plus® Dural Regeneration Matrix – Spinal Matrix and Integra™ SpinalMend™ Dural Regeneration Matrix
Common Name:	Dural Graft Matrix
Classification Name:	Dura Substitute, Product Code GXQ Class II Regulation Number 882.5910

Substantial Equivalence:

DuraGen Plus® Dural Regeneration Matrix - Spinal Matrix and Integra™ SpinalMend™ Dural Regeneration Matrix are substantially equivalent in function and intended use to the currently marketed DuraGen Plus® Dural Regeneration Matrix (K032693).

Device Description:

DuraGen Plus® Dural Regeneration Matrix - Spinal Matrix and Integra™ SpinalMend™ Dural Regeneration Matrix are absorbable implants for the repair of dural defects. They are easy to handle, soft, white, pliable, nonfriable, porous collagen matrices. DuraGen Plus® Spinal Matrix and Integra™ SpinalMend™ are supplied sterile, non-pyrogenic, for single-use. The package

contains two (2) 1 inch (2.5 cm) by 3 inch (7.5 cm) DuraGen Plus® devices in double peel packages.

Intended Use:

1. DuraGen Plus® Dural Regeneration Matrix – Spinal Matrix is indicated as a dura substitute for the repair of dura mater.

2. Integra™ SpinalMend™ Dural Regeneration Matrix is indicated as a dura substitute for the repair of dura mater.

Comparison to Predicate:

DuraGen Plus® Dural Regeneration Matrix - Spinal Matrix and Integra™ SpinalMend™ Dural Regeneration Matrix are substantially equivalent in function and intended use to the currently marketed DuraGen Plus® Dural Regeneration Matrix (K032693) as delineated in **Table 1.**

Table 1: Substantial Equivalence Chart

Feature	Predicate : DuraGen Plus® Dural Regeneration Matrix	DuraGen Plus® Dural Regeneration Matrix – Spinal Matrix and Integra™ SpinalMend™ Dural Regeneration Matrix
Manufacturer	Integra LifeSciences Corporation	Integra LifeSciences Corporation
510(k)	510(k) K032693	Not yet assigned
Indications for Use	Dura Substitute DuraGen Plus® Dural Regeneration Matrix is indicated as a dura substitute for the repair of dura mater.	Same

Feature	Predicate : DuraGen Plus® Dural Regeneration Matrix	DuraGen Plus® Dural Regeneration Matrix – Spinal Matrix and Integra™ SpinalMend™ Dural Regeneration Matrix
Contraindications	DuraGen Plus ® Dural Regeneration Matrix is not designed, sold or intended for use except as described in the indications for use and is contraindicated in the following situations: For patients with a known history of hypersensitivity to bovine derived materials. For repair of spinal neural tube defects; anterior spinal surgery with dural resection (e.g., transoral surgery). Should be used with caution in infected regions. Not recommended to cover dural defects involving mastoid air cells. Not recommended for large defects at the skull base following surgery.	Same
Design		
Physical Structure	Collagen matrix that is 1 inch (2.5cm) x 3 inch (7.5cm) in dimension (average of 3.5mm in height), that is packaged in a single sterile inner blister tray with one (1) well to hold the device, and sealed within an outer blister tray.	Configuration comprised of two (2) units of the currently marketed 1 inch (2.5cm) x 3 inch (7.5cm) predicate collagen matrix, in which the two (2) units are packaged together in a single sterile inner blister tray with two (2) wells to hold each device, and sealed within an outer blister tray.

Assessment of Performance Data:

Since DuraGen Plus® Spinal Matrix and Integra™ SpinalMend™ are identical to DuraGen Plus® Dural Regeneration Matrix, except for modifications relating to the packaging configuration, testing in support of the modifications included a packaging validation, shipping validation, and design validation.

Conclusion:

Valid scientific evidence through physical property testing and upon review of published clinical evidence provide reasonable assurance that the DuraGen Plus® Dural Regeneration Matrix – Spinal Matrix and Integra™ SpinalMend™ Dural Regeneration Matrix are safe and effective under the proposed conditions of use, and are, with respect to intended use and technological characteristics, substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Integra Lifesciences Corporation
c/o Ms. Candice Arner
Regulatory Affairs Associate
311 Enterprise Drive
Plainsboro, NJ 08536

JAN 21 2010

Re: K092388
Trade/Device Name: DuraGen Plus® Dural Regeneration Matrix – Spinal Matrix and Integra™ SpinalMend™ Dural Regeneration Matrix
Regulation Number: 21 CFR 882.5910
Regulation Name: Dura Substitute
Regulatory Class: Class II
Product Code: GXQ
Dated: December 18, 2009
Received: December 22, 2009

Dear Ms. Arner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kevia Alexander for

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number: K092388

Device Name: DuraGen Plus® Dural Regeneration Matrix – Spinal Matrix and Integra™ and SpinalMend™ Dural Regeneration Matrix

Indications for Use:

DuraGen Plus® Dural Regeneration Matrix – Spinal Matrix is indicated as a dura substitute for the repair of dura mater

Integra™ SpinalMend™ Dural Regeneration Matrix is indicated as a dura substitute for the repair of dura mater

Prescription Use _X____ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K092388